Export Controls at CSU - Grant Calhoun, J.D.
Export Control Administrator

“Export” May Not Mean What You Think It Means

To most people, and understandably so, “export control” conjures up scenes of federal agents stopping shipments of missiles from being smuggled out of the U.S., or spies caught at the airport with national secrets hidden in their shoe. It’s true, export controls include the monitoring of international shipments for sensitive equipment and technology leaving the U.S., but that is really the smallest part of a larger concern for U.S. universities.

In fact, export control is one of the fastest-growing areas of concern for colleges and universities. The federal government has a slew of laws and regulations that either require advance governmental permission or completely prohibit U.S. citizens and green card holders from transferring particular items and technology - including information itself - outside the United States.

What’s more, the federal government has a broad definition of export that includes not just physical shipments from the U.S. to country X, but also the transmission of technical data or know-how to citizens of country X while inside the U.S., even right here on campus. This is called a “deemed” export, and it is one of the trickier areas to monitor at a large research university like CSU.

Which Information and Technologies are Controlled?

The government, as you might expect, has complex regulations covering military technology and equipment. But there are also fairly extensive controls on non-military equipment considered to be “dual-use”, or of a nature that could be modified to serve an improvised military use. Examples include things like lasers, satellites, radars, select biological agents, computers—even the remote entry fobs you might have on your car keys! Thankfully, these items are only export controlled to certain countries, though the particular locations will vary from item to item. The export control administrator can help you identify the controls on your technology.

Quick: Which of these is a violation of federal law?

- Conducting research with non-U.S. graduate students,
- Shipping materials to research partners abroad,
- Traveling internationally to present at a conference.

The correct answer is: maybe any of them! Normally, these activities do nothing but further the expansion of knowledge and help keep the business of higher education moving forward. However, it’s important to know when seemingly common practices can expose you to serious federal penalties.
The Fundamental Research Exception: A Researcher’s Best Friend

We all want the best and brightest working with and for us here at CSU, and sharing information is part of the University’s mission. The government understands this, and accordingly provides an exception to most export rules for “fundamental” university research, in which the results are broadly shared and published, as is most research done at CSU. However, publication restrictions imposed by a research sponsor, restrictions on the participation of foreign students, and proprietary information protections in a grant or contract can destroy this exception, putting research that is commonly assumed to be uncontrolled under federal scrutiny. To involve foreign individuals on research that is not considered “fundamental,” a license must be applied for from the federal government in advance of disclosing any export-controlled technology.

When You Go Overseas… Leave your Research Behind

When you travel abroad, the information you take goes with you just as if you shipped it there by boat. Are you taking any unpublished research, technical data, or perhaps proprietary data belonging to CSU or an industry partner? In this age of breathtaking advances in information theft, you may have data stolen from you and never realize it. Travelers also need to know that even if no one accesses the information, even if you don’t access it while traveling abroad, the government still considers that the information is exported.

Know Where to Get Help!

What happens if you get in trouble? Along with potential fines of up to $1,000,000 or time in prison, you may also lose your ability to receive governmental funds of any kind—including research dollars from federal agencies—for life. To complicate matters, the government’s rules and prohibitions differ from one country to the next, including comprehensive embargoes on places like Iran and Cuba, and other more targeted restrictions like prohibitions on sending military technology to China and India. These may all still be avoided if a license is granted, but it is important to contact the Export Control Administrator in advance of any export.

Export control regulations are complicated, extensive, and do not make for a spellbinding read. It is not your job to become an expert on export controls—but it is your job to ask questions and seek assistance when these matters arise.

The Export Control Administrator works with all members of the CSU community to help ensure compliance with laws around technical research, international shipping, export licensing, international travel, and safe business transactions. Don’t be afraid to ask questions or get help—the only mistake is ignoring the issue. Reduce the risk to yourself and CSU by contacting the Export Control Administrator at Grant.Calhoun@colostate.edu, or visit http://web.research.colostate.edu/OSP/export.aspx to learn more.

Want to learn more? Consider attending the next Export Control Training Session:

Export Controls at CSU: The basics and your questions answered
Tuesday, April 8, 10:00–11:00 a.m. – Morgan Library Event Hall, 1st Floor
No registration is required. Light refreshments will be served.
IBC Training Update

Important changes to BSL3 training requirements

In an effort to streamline Biosafety Training for BSL3 laboratories, the following changes have been made:

- Effective immediately, Unit 1b is no longer available. This is now replaced by BSL3 Concepts combined with BSL1 and 2 Online Training. The title of the new online training course is “BSL1, 2, and 3 Concepts Training” and can be found online on the EHS training database:
  

  Please note, users who take the “BSL1, 2, and 3 Concepts Training” are no longer required to take “BSL1 and BSL2 Online Training” as this material is covered in the concepts training.

- Effective immediately, the Mock BSL3 Refresher Training (also known as Unit 3 refresher) is now available online! The title of this new training course is “BSL3 Lab and Cabinet Refresher Training”; the power point slides and quiz can be found on the EHS training database [https://wsnet.colostate.edu/cwis86/WTrainReg/ClassSignUp.aspx?TabID=Biosafety](https://wsnet.colostate.edu/cwis86/WTrainReg/ClassSignUp.aspx?TabID=Biosafety). This refresher training must be taken annually. For those still wishing to take the face-to-face Mock BSL3 Refresher Training, please contact Heather Blair (Heather.Blair@colostate.edu).

As a reminder, PIs are responsible for in-barrier training of their supervisees. The PI may delegate the training to another qualified user; however the PI is ultimately responsible for ensuring that their laboratory personnel have been properly trained. In addition, the PI is responsible for keeping up to date training records for individuals in their lab and must be able to make those records readily available to the Biosafety Office upon request.

To assist with maintaining these training records, an online database has been developed where PIs (or delegates) can log in the training information for individuals in their lab. This database [www.vivo.colostate.edu/training](http://www.vivo.colostate.edu/training) is available for PIs and their lab personnel to use.

For questions regarding how to use this database, please contact Dr. Richard Bowen (Richard.Bowen@colostate.edu).

The IBC and the BSO strongly believe that these changes will help reduce training times. If you have any questions regarding these changes, please contact Christine Johnson (Christine.Johnson@colostate.edu).

RICRO Associate Director Search

The process to select an Associate Director for RICRO is nearing completion. We had an excellent pool and hope to make the announcement shortly. Thank you to the candidates, members of the search committee, and members of the division and compliance committees who attended the interviews and met with the candidates. Your time and feedback in this process have been much appreciated.
RICRO Staff Notes

IACUC

An important change to RICRO’s personnel is coming in mid-April. Our Senior IACUC Coordinator, Bill Moseley, has accepted a position in CSU’s Office of Sponsored Programs effective the middle of April. Bill’s departure will be very sad for RICRO, but represents an exciting opportunity and we wish him all the best. Bill will likely continue on with RICRO in a part-time capacity though the end of April. Elaine Kim will be handling the IACUC workload until we can get new personnel onboard.

IRB

The Spring semester usually brings a flurry of human subjects research activity and an accompanying heavy load of new IRB protocols, continuing reviews, and amendments. The coordinators always recommend that you submit any new protocol at least a 4-6 weeks in advance of when you wish to begin your study to give the IRB members and coordinators sufficient time to complete the review. This is especially important now, as Janell Barker (Senior IRB Coordinator at CSU for over ten years) is taking extended family leave for the next few weeks. In Janell’s absence, Evelyn Swiss will be handling all new expedited and full-board protocol submissions. Please continue to plan ahead, and be sure to contact Evelyn if your start date is sensitive. RICRO staff have stepped up to help with IRB duties where needed, so you may be receiving emails from other RICRO staff members while IRB staffing is determined.

Front Office

Claire Calhoun joined the RICRO team in Fall 2013, becoming the newest work-study Administrative Assistant. Claire is working on her second Bachelor’s Degree in Nutrition and Food Science. She has been a tremendous help with office affairs, and we so appreciate her Excel mastery and extensive skills in customer service! In her free time, Claire is a volleyball enthusiast.

IT Staff

Daniel Lennox is our newest member of the RICRO team as our Student IT Tech. Daniel is a freshman, Computer Engineering major joining us from Canon City, Colorado. We are happy to bring Daniel into RICRO and are excited for his ability to grow with us throughout his collegiate career. Dan enjoys hunting and fishing in his free time. Welcome aboard, Dan!

Ryan Deming - We would also like to say a big “thank you!” and “good luck!” to our former IT student Ryan Deming who is headed off into the working world. Ryan worked for us about a year and a half as our local IT help and has now graduated from CSU. We will miss Ryan's joyful spirit around the office and wish him the best of luck in his future endeavors (and job search!).
**Spring 2014 Semi-Annual Animal Care and Use Facility Inspections**

The spring 2014 semi-annual animal care and use facility inspections are approaching—they will occur during the month of April. Members of the IACUC will visit all facilities where animals are housed and taken for procedures. Principal Investigators (PIs) working with animals outside the central facilities will be contacted by RICRO staff regarding the timing of the inspections teams visiting the various facilities. The IACUC asks that PIs and Study Directors make themselves available during the inspection time. A tip sheet for preparing for semi-annual inspections can be found at:

http://ricro.colostate.edu/IACUC/Documents/LaboratoryPreparationfortheSemi-AnnualInspection.pdf

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**IACUC Post-Approval Monitoring Pilot to Continue under the Direction of Dr. M. Lynne Kesel**

As you should have heard from the announcement emailed to all PIs of animal care and use protocols, the pilot Post-Approval Monitoring Program (PAM) will be continued for the next 5-6 months. The Vice President for Research has reassigned Dr. Lynne Kesel to shepherd the pilot PAM Program until the institution can further evaluate the activities. We are fortunate to have someone of Dr. Kesel’s experience and expertise in laboratory animal medicine to help continue the program.

During this interim period the Program will seek to have laboratory visits to observe animal procedures and to look over protocol records. Because there would not be time for Dr. Kesel to visit all laboratories for all 600 of our active protocols, they will be prioritized so that protocols utilizing USDA-regulated species and pain categories D and E will be visited first.

As the VPR stressed in his letter announcing the program, the intent of the PAM visits is not “compliance for compliance sake,” but rather the recognition of the fact that as science moves forward animal experiments may need to be adjusted. The PAM program is intended to assist researchers to maintain compliance, not to be a “gotcha” situation. However, in order to fulfill the regulatory requirements, non-compliances noted during the visits will be assessed by the IACUC and if they meet the regulatory threshold for reporting, the institution is required to report them to the appropriate federal agencies.

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**eProtocol Tips - Closing Your Protocol**

**IRB** - Have you recently received a reminder email to renew or close your IRB protocol? If you are debating whether to close or submit a continuing review, remember that you can close your protocol, even while continuing to analyze data, as long as you are no longer analyzing data that contain identifiers. To close your IRB protocol: 1. Click on the ID#; 2. Select to “Start Final Report”; 3. Respond to the initial group of Yes/No questions; 4. Click “Continue” 5. Complete the one-page Final Report; 6. Click “submit form.” See the Final Report tip sheet and other helpful eProtocol tip sheets & FAQs here (look under “Additional Information” at the end of the FAQs for the tip sheets):

http://ricro.colostate.edu/IRB/eProtocolTips.html

**IACUC** - When you are submitting a 4th-year renewal, please remember to also submit a closure form for the old protocol. There’s a handy option you can select on the closure form that says “4th-Year Renewal Submitted, close when renewal approved.” Please select that option and submit your Closure as soon as you’ve submitted the 4th Year Renewal. There is a tip for Closures and other types of submissions at http://ricro.colostate.edu/IACUC/TipsGuidance.html.
**ClinicalTrials.gov Basics**

**What is ClinicalTrials.gov?** ClinicalTrials.gov is an on-line site where you can register your human subjects trial information and results. Operated by the United States National Library of Medicine (NLM), there is no charge to register your trial. Although there are many clinical trial registries in operation, ClinicalTrials.gov was the first registry for clinical trials and is now the largest and most widely used registry. You can register both intervention and behavioral research trials at www.ClinicalTrials.gov

**What is the purpose of trial registers?** Clinical trials registries were developed to make human subject research data more transparent and publicly available. They are designed to ensure that clinical trial information, data and status are available to all those involved in health-care decision making and are intended to ultimately strengthen the validity and value of the scientific evidence base.

ClinicalTrials.gov is open to public access and is easily searchable. For example, trials can be searched by disease/indication, drug, location, etc. With the goal of promoting increased transparency and access to clinical trials, clinical trial registries encourage trial information to be made available to the public as early as possible, specifically to make this information available *prior to* registering the first subject on the trial (revised Declaration of Helsinki, October 2008).

**Why is this important to CSU Investigators?** In addition to participating in the world-wide movement of increased transparency in research and ensuring access to human subject data, the International Committee of Medical Journal Editors (ICMJE) decided that from July 1, 2005 no trials will be considered for publication unless trial information and results have been registered on a clinical trials register. This means that to publish research in ICMJE journals on safety and efficacy data for health interventions, as well as many observational studies, you must register your trial prior to publication and, as required by the revised Declaration of Helsinki, your trial should be registered prior to enrolling the first subject.

We advise you to review the publication policies of the Journals of interest to your research for their publication policy with regard to trial registration. To see Frequently Asked Questions regarding the ICMJE policy visit:

[http://www.icmje.org/faq_clinical.html](http://www.icmje.org/faq_clinical.html)

For a listing of Journals that follow the ICMJE's Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals visit:

[http://www.icmje.org/journals.html](http://www.icmje.org/journals.html)

For more information on access to ClinicalTrials.gov or assistance in registering your trial contact: Cat Bens in RICRO.

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**ClinicalTrials.gov**

A service of the U.S. National Institutes of Health
## Schedule of Events

**March - May 2014**

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<tr>
<td>5 IBC Deadline 12:00pm</td>
<td>2 IBC Deadline</td>
<td>7 IBC Deadline 12:00pm</td>
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<tr>
<td>10 RCR Authorship &amp; Publication Workshop</td>
<td>8 IACUC Deadline 12:00pm</td>
<td>8 IRB Deadline</td>
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<td>11 IACUC Deadline 12:00pm</td>
<td>9 IBC Meeting</td>
<td>13 IACUC Deadline 12:00pm</td>
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<tr>
<td>12 IBC Meeting</td>
<td>14 Basic Research Techniques with Mice - UV</td>
<td>15 IRB Deadline</td>
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<tr>
<td>12 Basic Research Techniques with Mice - UV</td>
<td>10 IRB Deadline 5:00pm</td>
<td>16 IRB Meeting</td>
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<tr>
<td>13 IRB Deadline</td>
<td>15 IRB On-campus Human Subjects Training 1</td>
<td>21 Basic Research Techniques with Mice - UV</td>
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<td>15-23 Spring Break</td>
<td>17 IRB Meeting</td>
<td>26 University Holiday - Closed</td>
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<td>20 IRB Meeting - Rescheduled to 3/27</td>
<td>22 IACUC Meeting</td>
<td>27 IACUC Meeting</td>
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<tr>
<td>25 IACUC Meeting</td>
<td>26 IRB On-campus Human Subjects Protection Training 9:30am-12pm</td>
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**Where to find RICRO**

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